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10/030,002	03/19/2002	Jean-Jacques Caboche	3-1032-170	5740
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YOUNG & THOMPSON 745 SOUTH 23RD STREET 2ND FLOOR ARLINGTON, VA 22202			EXAMINER OLSON, ERIC	
			ART UNIT	PAPER NUMBER
			1623	
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			01/28/2008	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

### Application No.

10/030,002

### Applicant(s)

CABOCHE ET AL.

### Examiner

Eric S. Olson

### Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 19-24 and 31-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19-24 and 31-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**Detailed Action**

In view of the appeal brief filed on November 23, 2007, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below.

  
SHAOJIA ANNA JIANG, PH.D.  
SUPERVISORY PATENT EXAMINER

This office action is a response to applicant's appeal brief submitted November 23, 2007. This application is a national stage application of PCT/FR00/01109, filed April 26, 2000, which claims priority to foreign application FR99-05523, filed April 30, 1999.

Claims 19-24 and 31-37 are pending in this application.

Claims 19-24 and 31-37 as amended are examined on the merits herein.

In view of Applicant's arguments in the appeal brief submitted November 23, 2007, the rejection of instant claims 19-24 and 31-37 under 35 USC 103(a) as being obvious over US patent 4454161 is withdrawn. Specifically, the above reference does not reveal or suggest a gelatinization step of over 130°C and 3.5 bars as recited in the instant claims.

The following new grounds of rejection are introduced:

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method involving certain specific branching enzymes, for example from *E. coli*, *C. reinhardtii*, or maize, does not reasonably provide enablement for a method utilizing any possible starch branching enzyme whatsoever expressed in any genetically modified expression system whatsoever. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The Applicant's attention is drawn to *In re Wands*, 8 USPQ2d 1400 (CAFC1988) at 1404 where the court set forth eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) The nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention: The claimed method is an *in vitro* biocatalytic reaction involving a purified enzyme. In order to use the claimed invention, one skilled in the art must possess the branching enzyme.

The state of the prior art: Various starch branching enzymes are known in the art from various organisms. In fact, these enzymes are common across a wide variety of species due to the ubiquity of starch as a storage medium. Some of these enzymes have been cloned and recombinantly expressed, and are useful for modifying the properties of starch *in vitro*. For example, enzymes from maize, *Bacillus megaterium*, and *Chlamidomonas reinhardtii*, have been isolated in this manner. However, the prior art does not reveal the isolation of each and every possible starch branching enzyme, or of a representative sample thereof.

Furthermore, while certain expression systems such as *E. coli*, yeast, or mammalian cell culture are well known in the art for expressing recombinant proteins, the prior art does not reveal the full scope of all possible genetically modified organisms that could be used to express an exogenous protein such as a starch branching enzyme.

The relative skill of those in the art: The relative skill of those in the art is high.

The predictability or unpredictability of the art: Discovering new genes in new organisms is an unpredictable task. Although one skilled in the art would have reason to suspect that many organisms possess an as yet undiscovered starch branching gene, finding that gene in the genomes of a wide variety of plants and microorganisms would involve difficult and unpredictable experimentation. Furthermore, the expression and purification of an enzyme, which is necessary in order to use it in the claimed method, is also difficult and unpredictable. According to Short Protocols in Molecular Biology, Third Edition, (Reference included in PTO-892) bacterial expression systems have several disadvantages, including lack of post-translational modification, formation of inclusion bodies, and inadequate excretion from the cell. Mammalian and baculoviral expression systems can overcome some of these disadvantages but are more difficult and time-consuming and are not adequate for the large-scale production of proteins. Each new starch branching enzyme would require further experimentation to determine the best method for expression and purification before it could be used in the claimed method.

Furthermore, in order to use any "genetically modified organism capable of expression said enzyme," one skilled in the art would have to develop a wide variety of recombinant expression systems involving a large number of unrelated organisms and tissue cultures. This process would be highly unpredictable as many organisms are not well characterized and their suitability for protein expression is not known.

Therefore the process of obtaining every starch branching enzyme would be highly unpredictable.

The Breadth of the claims: The claimed invention is very broad, encompassing all starch branching enzymes. There is no particular limitation on the species from which the enzyme is extracted or its structural or physical properties.

The amount of direction or guidance presented: The claimed specification suggests the use of certain existing starch branching enzymes. In addition, a general strategy is suggested for the use of polyclonal antibodies to discover new enzymes related to existing algal starch branching enzymes.

The presence or absence of working examples: The working examples provided use one specific enzyme, obtained from *Chlamidomonas reinhardtii*.

Note that lack of working examples is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art such as the discovery, purification, and expression of new enzymes. See MPEP 2164.

The quantity of experimentation necessary: In order to practice the full scope of the invention with every possible starch branching enzyme, one skilled in the art would have to identify a vast range of different enzymes, and express and purify them in a form suitable for use. Because the prior art does not teach expression and purification of every possible enzyme, many of these techniques would have to be developed from scratch. Although some of these enzymes have been successfully used for *in vitro* biocatalysis, finding optimal expression and purification methods for all of the remaining enzymes would be difficult and unpredictable as discussed above. Furthermore, using all possible genetically modified organisms as expression systems would provide an

equally great and unpredictable burden of experimentation. Therefore practicing the full scope of the invention would require an undue burden of unpredictable experimentation.

*Genentech*, 108 F.3d at 1366, states that, "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion." And "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Therefore, in view of the Wands factors, as discussed above, particularly the lack of guidance or working examples and the unpredictability of the art, Applicants fail to provide information sufficient to practice the claimed invention for all possible enzymes and expression systems.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Okada et al. (US patent 4454161, of record in previous office action) in view of Senkeleski et al. (US patent 5562937, cited in PTO-892) Okada et al. discloses a branched alpha-glucose polymer (starch) produced by the activity of a branching enzyme, for example an animal, plant, or microorganism branching enzyme in a starch such as amylopectin. (column 1 lines 47-63) A gelatinized solution of the starch is



subjected to the action of the branching enzyme and then used, after concentration and/or drying, in food products. (column 2, lines 5-20) A bacillus branching enzyme is reported (column 5, lines 15-23) having an optimal temperature of about 25C and being stable up to about 45C. (column 6 lines 39-49) These starches display a reduced propensity for retrogradation. (column 2, lines 21-31) Okada et al. does not disclose a method in which the starch is gelatinized by a treatment at over 130°C and 3.5 bars as recited in the instant claims. Okada et al. also does not explicitly disclose a method in which the amount of branching enzyme is between 50-2000 units and the reaction is carried out at exactly 30°C.

Senkeleski et al. discloses a method for digesting waxy starch with beta-amylase. (column 1, lines 40-58) The starch, in order to be processed in this manner, is first steam cooked at a temperature of 120°C to 170°C at a pressure of 60-80 psi, which is equivalent to about 4.1-5.5 bar.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the gelatinization process of Senkeleski et al. to pre-gelatinize the starch, for example amylopectin, before the enzymatic step of Okada et al. One of ordinary skill in the art would have been motivated to use this gelatinization step because Okada et al. already teaches the use of a gelatinization step before the enzymatic digestion, and because the gelatinization of Senkeleski et al. is shown to be useful for gelatinizing starch in preparation for enzymatic digestion. One of ordinary skill in the art would reasonably have expected success because gelatinization procedures

are routine and well known in the art, and choosing an appropriate procedure would be well within the ordinary and routine level of skill in the art.

Furthermore, it would have been obvious to one of ordinary skill in the art to optimize the amount of branching enzyme, and reaction temperature and duration to arrive at the values discussed in the instant claims. One of ordinary skill in the art would have been able to choose optimal values for these experimental parameters through a simple process of routine optimization, and would clearly have recognized reaction time, temperature, and amount of catalyst to be result-effective variables that could be varied to produce the desired result.

Therefore the invention taken as a whole is *prima facie* obvious.

Claims 31-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Okada et al. (US patent 4454161, of record in previous office action) in view of Senkeleski et al. (US patent 5562937, cited in PTO-892) as applied to claims 19-22 above, and further in view of Sandström et al. (PCT international publication WO95/22562, reference included with PTO-1449, also published as Brynolf et al. (US patent 5929052, cited in PTO-892) The disclosures of Okada et al. and Senkeleski et al. are discussed above. Okada et al. and Senkeleski et al. do not disclose a composition having the characteristics described in instant claims 31-37.

Sandström et al. discloses a branched starch (alpha-glucose polymer) having a molecular weight ranging from  $1.5 \times 10^4$  to  $10^7$  daltons, corresponding to the limitations in instant claim 31. (p. 3, lines 16-24) These starches have a branching degree of about 2-

8%, preferably 3-7%. (p. 4, lines 1-3) A starch with this molecular weight will possess less than 1% reducing sugars, as there will be only one reducing end per molecule. The starch is particularly stable in solution, (p. 2 lines 25-31) and will therefore have a low tendency to retrograde in solution. These molecules are also considered to possess the claimed viscosity of at most 5000 cP in view of the fact that they possess the same structural characteristics (size, degree of branching) as those described in the instant specification. (for example p. 21, table II of the instant specification) It is noted that the starches of Sandström et al. differ from the claimed invention in that they possess beta-glycosidic linkages as a result of the specific method of acid treatment used to increase the branching degree.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the method of Okada et al. in view of Senkeleski et al. to produce a branched product as described by Sandström et al., having the same molecular weight and degree of branching but lacking beta-glycosidic bonds. One of ordinary skill in the art would have recognized that the enzymatic treatment of Okada et al. in view of Senkeleski et al. produces the same result, namely increased branching, as the acid treatment of Sandström et al., and that the two treatments are therefore interchangeable. With regard to the presence of beta-glycosidic bonds in the compounds of Sandström et al., this structural feature is an incidental result of the particular acid treatment used, and is not seen to be necessary for the desired properties, namely stability and reduced osmolality, present in the starches of Sandström et al. One of ordinary skill in the art would reasonably have expected

success because the method of Okada et al. in view of Senkeleski et al. is already seen to be useful for increasing the branching degree of a starch.

Furthermore, it would have been obvious to one of ordinary skill in the art to optimize the various characteristics of the starch of Sandström et al., such as degree of branching and molecular weight, to arrive at the values discussed in instant claims 32, 36, and 37. One of ordinary skill in the art would have been able to choose optimal values for these experimental parameters through a simple process of routine optimization, and would clearly have recognized these structural properties to be result-effective variables that could be varied to produce the desired solution properties in the final product.

Therefore the invention taken as a whole is *prima facie* obvious.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 19-22 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of copending Application No. 7015318. (Cited in PTO-892, herein referred to as '318) Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-4 of '318 anticipate the claimed invention. These claims are drawn to a method wherein a starch is gelatinized under heating, cooled, and treated with a branching enzyme. According to claims 3-4 these enzymes are introduced at between 20-70 C, and include starch branching enzymes. While the language used in the claims is somewhat generic, the specification of '318 further defines the gelatinization step as involving heating the starch to between 110-170C, and the branching enzyme as being extracted from higher plants, yeasts, bacteria, and algae. (column 4, lines 33-38) Example 1 (column 6, lines 15-65) discloses an experimental method falling within the methods of instant claims 19-21 and producing products B and C identical to instant claims 31-37. Therefore the claims 1-4 of '318 are properly interpreted as including gelatinization and digestion steps falling within the limitations of instant claims 19-22.

Furthermore, it would have been obvious to one of ordinary skill in the art to optimize the amount of branching enzyme, and reaction temperature and duration to arrive at the values discussed in the instant claims. One of ordinary skill in the art would have been able to choose optimal values for these experimental parameters through a

simple process of routine optimization, and would clearly have recognized reaction time, temperature, and amount of catalyst to be result-effective variables that could be varied to produce the desired result.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### **Conclusion**

No claims are allowed in this application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Eric Olson



Patent Examiner

AU 1623

1/15/08

Anna Jiang



Supervisory Patent Examiner

AU 1623